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| 10/069,107 | 12/16/2002 | Andrew H Cragg | 032005-130 | 3240 |

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| EXAMINER | |
|---|---|
| SZMAL, BRIAN SCOTT | |
| **ART UNIT** | **PAPER NUMBER** |
| 3736 | |

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/069,107 | CRAGG ET AL. | |
| | Examiner | Art Unit | |
| | Brian Szmal | 3736 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) 29-41 is/are allowed.

6)☒ Claim(s) 1-28,42 and 43 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10-14-03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

### *Claim Objections*

1. Claim 7 is objected to because of the following informalities: The claim recites the use of "a tapered shape" in line 2 of the claim. However, in Claims 8-10, of which depend upon Claim 7, recite "the tapered surface". Therefore, in Claim 7, "a tapered shape" appears it should read as "a tapered surface" to provide proper antecedent basis for Claims 8-10. Appropriate correction is required.

2. Claims 13-15 are objected to because of the following informalities: The claims utilize claim language such as "is made of", which constitutes product-by-process language. In order to overcome the objection, the claim language should be changed to "comprises". Appropriate correction is required.

### *Claim Rejections - 35 USC § 102 & 35 USC § 103*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-6, 11 and 16-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cragg et al (6,162,192). Cragg et al disclose a system for facilitating hemostasis of blood vessel punctures and further disclose an elongated member including a distal end and a proximal end, the distal end having a means for locating the blood vessel while impeding the distal end of the elongated member from entering the blood vessel; the elongated member has a constant outer diameter; the elongated member has an outer diameter which progressively decreases to a smaller diameter at the distal end; the elongated member has a lumen extending from the distal end to the proximal end; the lumen is centered within the elongated member; the outer diameter of the lumen at the distal end is about 50-99% of the outer diameter of the elongated member; a depth indicating member positioned on an exterior of the elongated member and movable in an axial direction with respect to the elongated member; the depth indicating member is an elastic ring; and an extending control member that extends from a tapered surface and beyond the distal end of the elongated member. See Column 3, lines 64-67; Column 4, lines 1-18; and Figure 2.

Regarding Claim 6, it would have been an obvious matter of design choice to place the lumen off-center along the longitudinal axis of the elongated member, since the Applicant does not disclose the criticality of the off-center placement of the lumen in relation to the disclosed centered placement of the lumen in the disclosure. Therefore, it would have been obvious to one of ordinary skill in the art that the centered lumen of

Cragg et al (6,162,192) would be able to perform the same function as that of the claimed off-center lumen.

6. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6,162,192) as applied to claim 4 above, and further in view of Cragg et al (6,315,753 B1).

Cragg et al ('192), as discussed above, disclose a system for facilitating hemostasis of blood vessel punctures, but fail to disclose the distal end of the lumen has a tapered surface; and the tapered surface has a substantially conic shape.

Cragg et al ('753) and disclose a system for facilitating hemostasis of blood vessel punctures and further disclose the distal end of the lumen has a tapered surface; and the tapered surface has a substantially conic shape. See Figure 26.

Since both Cragg et al ('192) and Cragg et al ('753) disclose means for sealing blood vessel punctures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Cragg et al ('192) to include the tapered surface of the lumen, as per the teachings of Cragg et al ('753), since it would provide a means of accessing the perimeter of the puncture site while providing a tactile feedback to the user.

Regarding Claim 9, it would have been an obvious matter of design choice to have the tapered surface at the distal end of the lumen be a substantially concave spherical shape, since the Applicant has failed to disclose the criticality of the concave surface, in relation to a conic shape, such that the shape provides an advantage, used for a particular purpose, or solves a stated problem. Therefore, it would have been obvious to

one of ordinary skill in the art that the tapered surface of Cragg et al ('753) would be capable of performing the same function as that of the claimed concave surface at the distal end of the lumen.

Regarding Claim 10, it would have been an obvious matter of design choice to have the tapered surface at the distal end of the lumen be a substantially stepped configuration, since the Applicant has failed to disclose the stepped configuration, in relation to other shapes, provides an advantage, used for a particular purpose, or solves a stated problem. Therefore, it would have been obvious to one of ordinary skill in the art that the tapered surface of Cragg et al ('753) would be capable of performing the same function as that of the claimed stepped configuration at the distal end of the lumen.

7. Claims 12, 19, 20, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6,162,192) as applied to claim 1 above, and further in view of Janzen (5,437,631).

Cragg et al, as discussed above, disclose a system for facilitating hemostasis of blood vessel punctures, but fail to disclose the lumen at the distal end has a diameter of about 0.050 to 0.160 inches; the extending control member includes a proximal end, a distal end and a lumen which extends from the proximal end to the distal end; the extending control member is configured to occlude and control a puncture in the blood vessel; the extending member extends form the tapered surface of the device by about 0.10 to 6.0 inches; and the extending member is formed from a flexible material to prevent the extending member from catching on subcutaneous tissue as the extending member advances through the patient's skin and tissue at the puncture site.

Janzen discloses a percutaneous introducer set and means for sealing a puncture, and further discloses the lumen at the distal end has a diameter of about 0.050 to 0.160 inches; the extending control member includes a proximal end, a distal end and a lumen which extends from the proximal end to the distal end; the extending control member is configured to occlude and control a puncture in the blood vessel; the extending member extends from the tapered surface of the device by about 0.10 to 6.0 inches; and the extending member is formed from a flexible material to prevent the extending member from catching on subcutaneous tissue as the extending member advances through the patient's skin and tissue at the puncture site. See Figures 1 and 2; Column 6, lines 63-65; and Column 7, lines 11-20.

Since both Cragg et al and Janzen disclose means for sealing puncture wounds, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Cragg et al to include the use of an extending control member per the teachings of Janzen, since it would provide a means of controlling the device during the procedure.

8. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6,162,192) as applied to claim 1 above, and further in view of Scribner (5,395,353).

Cragg et al, as discussed above, disclose a system for facilitating hemostasis of blood vessel punctures, but fail to disclose the elongated member is made of a material with a hardness of at least 50 D; a portion of the elongated member is made of a friction reducing material; and the elongated member is made of a friction reducing material.

Scribner discloses a guiding catheter with controllable perfusion ports and further disclose the elongated member is made of a material with a hardness of at least 50 D; a portion of the elongated member is made of a friction reducing material; and the elongated member is made of a friction reducing material. See Column 7, lines 18-21. Since both Cragg et al and Scribner disclose means for accessing blood vessels, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the disclosure of Cragg et al to include the use of polyurethane as the material for the elongated member, as per the teachings of Scribner, since it is well known in the art that polyurethane has a hardness of at least 50 D and is also a low friction material.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6,162,192) and Janzen (5,437,631) as applied to claim 19 above, and further in view of Tay et al (6,063,085).

Cragg et al and Janzen, as discussed above, disclose means for sealing blood vessel punctures, but fail to disclose the distal end of the extending member has at least one vent hole for allowing fluid to enter the lumen of the extending member.

Tay et al disclose an apparatus for sealing vascular punctures, and further disclose the distal end of the extending member has at least one vent hole for allowing fluid to enter the lumen of the extending member. See Column 18, lines 15-25.

Since Cragg et al, Janzen and Tay et al disclose means for sealing blood vessel punctures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Cragg et al and Janzen to include the

use of a vent hole in the extending member, as per the teachings of Tay et al, since it would provide a visual indication to the operator of the depth from the incision to the puncture.

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6,162,192) and Janzen (5,437,631) as applied to claim 19 above, and further in view of Brenneman et al (5,645,566).

Cragg et al and Janzen, as discussed above, disclose means for sealing blood vessel punctures, but fail to disclose the lumen tapers from a first diameter at the proximal end to a second smaller diameter at the distal end.

Brenneman et al disclose a means for sealing blood vessel punctures and further disclose the lumen tapers from a first diameter at the proximal end to a second smaller diameter at the distal end. See Figure 1B.

Since Cragg et al, Janzen and Brenneman et al disclose means for sealing blood vessel punctures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Cragg et al and Janzen to include a tapering lumen, as per the teachings of Brenneman et al, since it would provide a means of preventing the accidental discharge of the hemostatic material from the lumen during the procedure.

11. Claims 25, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janzen (5,437,631) in view of Fowler (5,601,602).

Janzen, as discussed above, disclose a means for sealing puncture wounds and further disclose a control member extending from the distal end of the elongated member and

configured to be received in the puncture site; the control member is tapered; and the control member has a tapered lumen. See Figures 1 and 2.

Janzen however fails to disclose an elongated member having a distal end, a proximal end, and a means at the distal end for locating the blood vessel puncture by capturing an edge of the blood vessel puncture.

Fowler discloses a means for sealing a blood vessel puncture and further disclose an elongated member having a distal end, a proximal end, and a means at the distal end for locating the blood vessel puncture by capturing an edge of the blood vessel puncture. See Figures 7 and 8; and Column 6, lines 3-12.

Since both Janzen and Fowler disclose means for sealing blood vessel punctures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Janzen to include the use of a means for capturing an edge of the blood vessel puncture, as per the teachings of Fowler, since it would provide a means of locating as well as anchoring the device during the procedure.

12. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Janzen (5,437,631) and Fowler (5,601,602) as applied to claim 25 above, and further in view of Tay et al (6,063,085).

Janzen and Fowler, as discussed above, disclose means for sealing blood vessel punctures, but fail to disclose a vent in the control member for venting fluid from the control member to the proximal end of the elongated member to provide an indication of the location of the member in the blood vessel.

Tay et al, as discussed above, disclose a means for sealing blood vessel punctures, and further disclose a vent in the control member for venting fluid from the control member to the proximal end of the elongated member to provide an indication of the location of the member in the blood vessel. See Column 18, lines 15-25.

Since Janzen, Fowler and Tay et al disclose means for sealing blood vessel punctures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Janzen and Fowler to include the use of a vent hole in the control member, as per the teachings of Tay et al, since it would provide a means of allowing the operator to determine the depth from the incision to the puncture through the visualization of the blood flowing through the proximal end of the device.

13. Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tay et al (6,063,085) in view of Cragg et al (6,162,192).

Tay et al, as discussed above, disclose a means for sealing blood vessel punctures, and further disclose introducing an elongated member through the incision; providing visual feedback of a general location of the blood vessel puncture by venting blood through an elongated member; and the visual feedback is provided by a control member at the distal end of the elongated member, the control member having a vent hole. See Column 18, lines 15-25.

Tay et al, however fail to disclose providing specific tactile feedback of the location of the blood vessel puncture by contact between the elongated member and the exterior of the blood vessel puncture.

Cragg et al, as discussed above, disclosed above, disclose a means for sealing blood vessel punctures and further disclose providing specific tactile feedback of the location of the blood vessel puncture by contact between the elongated member and the exterior of the blood vessel puncture. See Column 3, lines 64-67; Column 4, lines 1-18; and Figure 2.

Since both Tay et al and Cragg et al disclose means for sealing blood vessel punctures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Tay et al to include the use of providing tactile feedback to the user, as per the teachings of Cragg et al, since it would provide both visual and tactile feedback to the user to determine the placement of the blood vessel puncture.

***Allowable Subject Matter***

14. The following is a statement of reasons for the indication of allowable subject matter: Claims 29-41 are allowable since no prior art could be found teaching or suggesting a method of determining a depth of an incision to a puncture in a blood vessel, comprising: locating the puncture in the blood vessel be receiving a portion of a wall of the blood vessel with the distal end, as claimed in Claim 29.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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